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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/816,651	WALT ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>05/01</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for priority under 35 U.S.C. 120 is acknowledged. However, the subject matter of the instant Claims 1-12 and 16 i.e. a substrate other than a fiber optic bundle, is not disclosed in the parent applications as required under 35 U.S.C. 112. Therefore, instant Claims 1-12 and 16 are not entitled to the filing date of any of the above cited application. The effective filing date of instant Claims 1-12 and 16 is the filing date of the instant application i.e. 23 March 2001.

Specification

2. The disclosure is objected to because of the following informalities: The first paragraph of the specification needs to be updated to reflect the U.S. Patent No. (i.e. 6,266,459) for parent application 09/450,829.

Appropriate correction is required.

Claim Objections

3. Claim 25 is objected to because of the following informalities: "well" should be in the plural form "wells".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12, 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite for the recitation "said array is spotted" because it is unclear whether the recitation is intended to describe the structure of the array or whether the recitation is intended to be a method step of spotting. Furthermore, if intended as a method step, it is unclear where in the method of Claim 1, the step of spotting is intended to be performed.

Claim 20 is indefinite for the recitation "said sample" because the recitation lacks proper antecedent basis in Claim 19.

Claim 22 is indefinite for the recitation "the product" because the recitation lacks proper antecedent basis in Claims 18 and 19.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al (WO 99/67641, published 29 December 1999).

Regarding Claim 1, Chee et al disclose the method of detecting a target analyte comprising providing an array comprising a substrate other than a fiber optic bundle (i.e. flat planar substrate, page 7, lines 15-32) and at least first and second sites comprising first and second reaction components (page 10, lines 14-24), contacting the array with a sample and detecting a change in an optical property around at least the first site as an indication of an interaction between the target and a reaction component (page 23, lines 1-22 and Claims 8-14).

Regarding Claim 2, Chee et al disclose the method wherein the target analyte is an enzyme (page 31, lines 31-35).

Regarding Claim 3, Chee et al disclose the method wherein the reaction components are enzyme substrates i.e. enzyme-specific interaction (page 10, lines 20-24 and page 34, lines 4-19).

Regarding Claim 4, Chee et al disclose the method wherein the reaction components are attached to microspheres with a non-cleavable linker (i.e. functional group, page 16, lines 1-18 and page 17, lines 6-13) and randomly distributed on the substrate (page 5, lines 24-27).

Regarding Claim 5, Chee et al disclose the method wherein the target analyte is an enzyme substrate i.e. the decoder binding ligand is a substrate (page 17, lines 15-34).

Regarding Claim 6, Chee et al disclose the method wherein the reaction components are enzymes i.e. identifier binding ligands (page 17, lines 15-34).

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Regarding Claim 7, Chee et al disclose the method wherein the target analyte is an enzyme inhibitor i.e. the decoder binding ligand is an inhibitor (page 17, lines 15-34).

Regarding Claim 8, Chee et al disclose the method wherein the reaction components are enzymes i.e. identifier binding ligands (page 17, lines 15-34).

Regarding Claim 9, Chee et al disclose the method wherein the first and second reaction components are attached to first and second microspheres randomly distributed on the substrate (page 5, lines 3-7 and 24-27).

Regarding Claim 10, Chee et al disclose the method wherein the reaction components are enzymes (page 17, lines 7-13 and 28-34).

Regarding Claim 11, Chee et al disclose the method wherein the substrate is selected from the group consisting of glass, composite materials, metals and plastics (page 7, lines 15-24).

Regarding Claim 12, Chee et al disclose the method wherein the microspheres are distributed on the substrate providing a pattern of microspheres as spots on the array and hence, providing a spotted array (page 9, lines 1-24).

8. Claims 19, 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Brenner (U.S. Patent No. 5,863,722, filed 7 June 1995).

Regarding Claim 19, Brenner discloses the method of detecting an enzymatic reaction comprising providing an array comprising an array substrate comprising discrete sites (i.e. positions, Column 25, lines 62-64) and a population of microspheres randomly distributed on the substrate comprising discrete oligonucleotides attached thereto, contacting the array with a

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composition comprising an enzyme (e.g. Fok I) and detecting a change in an optical property around at least the first site as an indication of an interaction between the enzyme and the oligonucleotide (Column 25, line 44-Column 26, line 50).

Regarding Claim 22, Brenner discloses the method wherein the product of the reaction comprises a label (Column 26, lines 46-50).

Regarding Claim 24, Brenner discloses the method wherein the substrate is glass (Column 25, lines 44-46).

9. Claims 1, 2, 10 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Ness et al (U.S. Patent No. 5,667,976, filed 14 February 1996).

Regarding Claim 1, Van Ness et al disclose the method of detecting a target analyte comprising providing an array comprising a substrate other than a fiber optic bundle (i.e. dipstick) and at least first and second sites comprising first and second reaction components (Column 10, lines 24-54), contacting the array with a sample and detecting a change in an optical property around at least the first site as an indication of an interaction between the target and a reaction component (Example 7, Column 21, line 20-Column 22, line 33).

Regarding Claim 2, Van Ness et al disclose the method wherein the target analyte is an enzyme (Column 6, lines 20-30 and Column 10, lines 49-54).

Regarding Claim 10, Van Ness et al disclose the method wherein the reaction components are enzymes (Column 6, lines 20-30 and Column 10, lines 49-54).

Regarding Claim 13, Van Ness et al disclose the method for detecting a target analyte comprising providing an array comprising an array substrate comprising discrete sites and a

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population of microspheres comprising at least a first and second subpopulation comprising reaction components (oligos) and detection molecule (biotin), contacting the array with a sample and detecting a change in optical property as an indication of interaction between the target and reaction component (Example 7, Column 21, line 20-Column 22, line 33).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 18, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner (U.S. Patent No. 5,863,722, filed 7 June 1995).

Regarding Claim 18, Brenner teaches method of detecting an enzymatic reaction comprising providing an array comprising an array substrate comprising discrete sites (i.e. positions, Column 25, lines 62-64) and a population of microspheres randomly distributed on the substrate comprising reaction component substrates (i.e. oligos) attached thereto, contacting the array with a composition comprising reaction component (e.g. restriction enzyme, ligase) and detecting a change in an optical property around at least the first site as an indication of an interaction between the enzyme and the oligonucleotide (Column 25, line 44-Column 26, line 50). Brenner teaches the method wherein enzyme substrate (i.e. oligo) is attached to the microsphere and the enzyme is added to the immobilized substrate, but they do

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not teach an immobilized enzyme. However, the courts have stated that a mere reversal of parts is an obvious variation to a prior art arrangement see *In re Gazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (MPEP § 2144.04 (VI) A). Therefore, the instantly claimed immobilized enzyme contacted with the enzyme substrate would have been obvious variation of the immobilized substrate contacted with the enzyme as taught by Brenner.

Regarding Claim 22, Brenner discloses the method wherein the product of the reaction comprises a label (Column 26, lines 46-50).

Regarding Claim 24, Brenner discloses the method wherein the substrate is glass (Column 25, lines 44-46).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 13-14 and 18-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39-40 and 51 of U.S. Patent No. 6,023,540. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of

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detecting a target analyte (e.g. enzyme) comprising providing populations of microspheres having functionalities, contacting the microspheres with a sample and detecting optical signal to determine presence of the analyte. The claims only differ in the arrangement of the limitations within the claims. For example, the instant claims recite a) providing an array comprising microspheres, b) contacting the array with a sample and c) determining the presence of the analyte. While the '540 claims recite, a) contacting a sample with a substrate (limited to an array in Claim 40) comprising microspheres and b) determining the presence of the analyte. Because the claims differ only in the arrangement of the limitations within the claims, the claims are not patentably distinct.

14. Claims 13-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14, 18 and 21 of U.S. Patent No. 6,266,459. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of detecting a target analyte (e.g. enzyme) comprising providing populations of microspheres having functionalities, contacting the microspheres with a sample and detecting optical signal to determine presence of the analyte. The claims only differ in the arrangement of the limitations within the claims. For example, the instant claims recite a) providing an array (limited to fiber optic bundle in Claim 23) comprising microspheres, b) contacting the array with a sample and c) detecting a signal around a microsphere to determine the presence of the analyte. While the '459 claims recite a) providing a population of microspheres distributed on a surface (limited to fiber optic bundle in Claim 2), b) contacting the microspheres with a sample, and c) detecting a signal around a microsphere to determine the presence of the analyte. Because the claims differ only in the arrangement of the limitations within the claims, the claims are not patentably distinct.

15. Claims 13, 18, 19 and 23-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17- 21 of U.S. Patent No. 6,327,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of detecting a target analyte comprising providing populations of microspheres having functionalities, contacting the microspheres with a sample and detecting optical signal to determine presence of the analyte. The claims only differ in the arrangement of the limitations within the claims. For example, the instant claims recite a) providing an array (limited to fiber optic bundle in Claim 23) comprising microspheres, b) contacting the array with a sample and c) detecting a signal around a microsphere to determine the presence of the analyte. While the '410 claims recite a) contacting a sample with a substrate (limited to fiber optic substrate in Claim 18) comprising microspheres and b) determining the presence of the analyte. Because the claims differ only in the arrangement of the limitations within the claims, the claims are not patentably distinct.

16. Claims 13, 18, 19 and 23-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-21 of copending Application No. 09/925,292. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of detecting a target analyte comprising providing populations of microspheres having functionalities, contacting the microspheres with a sample and detecting optical signal to

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determine presence of the analyte. The claims only differ in the arrangement of the limitations within the claims. For example, the instant claims recite a) providing an array (limited to fiber optic bundle in Claim 23) comprising microspheres, b) contacting the array with a sample and c) detecting a signal around a microsphere to determine the presence of the analyte. While the '410 claims recite a) contacting a sample with a substrate (limited to fiber optic substrate in Claim 18) comprising microspheres and b) determining the presence of the analyte. Because the claims differ only in the arrangement of the limitations within the claims, the claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. Claims 14-16, 20-21 and 23-25 are free of the prior art of record and may be placed in condition for allowance following resolution of the above rejections.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878 until 13 January 2004. Starting 14 January 2004, the examiner's phone number will be (517) 272-0741. The examiner can normally be reached on 6:00 TO 3:30 Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 25, 2003